

**IN THE DRAWINGS**

Please replace Figure 8 (8/13) of the application as filed with replacement Figure 8 (Replacement Sheet 8/13) herewith enclosed.

## **REMARKS**

Claims 1, 11, 12, 15, 22, 26, and 31 are currently amended.

### **Drawings**

Applicants herewith submit new drawing, Figure 8, Sheet 8/13, labeled “Replacement Sheet” and a sheet showing changes labeled “Annotated Sheet” in compliance with 37 CFR § 1.121(d). Applicants have amended Figure 8 to include a marker, reference numeral 31. Support for the amendment of Figure 8 is to be found in the specification at page 13, paragraph 55, at page 18 paragraph 78, lines 4-7, at page 28, paragraph 112, lines 1-2 where the term “marker” is recited. No new matter is hereby entered with this amendment.

### **Specification**

Applicants have amended the specification at page 18 to include element number 31 (“marker”) of the elements identified on Figure 8, as amended. No new matter is hereby entered with this amendment.

### **Claims**

Applicants have amended claims 1, 22, 26, and 31 to include the limitation of a marker, reference numeral 31. Support for the amendments to claims 1, 22, 26, and 31 is to be found in the specification at page 13, paragraph 55, at page 18 paragraph 78, lines 4-7, at page 28, paragraph 112, lines 1-2.

Applicants have amended claims 11, 12, and 15 to be written in independent form including all the limitations of the base claim and any intervening claims.

No new matter has been added by these amendments.

Applicants respectfully request entry of the present amendments.

Claim Rejections under 35 USC § 102(b)

1) The Examiner has rejected claims 1-10, 13-14, and 22-30 under 35 USC § 102(b) as being anticipated by Saab (USPN 5,624,392).

The Examiner stated that Saab discloses a heat exchange catheter system for cooling a target organ as recited in claims 1, 2, 8, and 9. The Examiner stated that the ultrasound probe of Saab inherently has a transducer. The Examiner also stated that as to claims 3, 4, and 8, Saab further discloses a thermal exchange composition within the balloon lumen. The Examiner then stated that further to claims 5 and 7, the system of Saab clearly is capable of being placed within the esophagus, the uterus, etc. as claimed. The Examiner then stated that further to claim 6, Saab further disclosed the heat exchange catheter system wherein the balloon is shaped and sized for placement in the anatomical structure selected from the group consisting of: the venous system. The Examiner then stated that, as to claims 13 and 14, Saab further discloses the heat exchange catheter system of claim 1 further comprising a third elongate tubular body and a guidewire. The Examiner then stated that as to claims 22-29, Saab discloses all the elements of the claims as presented therein where the saccular body is the balloon which forms a flexible and elastic reservoir. The Examiner finally states that further to claim 30, the disclosure by Saab of water or saline as a fluid for circulation and cooling/heating inherently requires a pump.

Anticipation under 35 U.S.C. 102(b) requires the presence in a single prior art disclosure of each and every element of a claimed invention, *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 USPQ2d 1766, 1767 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988).

Applicants respectfully submit that Saab does not disclose a heat exchange catheter system for cooling a target organ comprising a marker. Applicants have amended claim 1 to recite: "A heat exchange catheter system for cooling a target organ, the heat

exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a transducer 29, (d) a marker 31, and (e) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”.

Applicants submit that claim 1 as amended is not anticipated by Saab. Applicants respectfully note that since claims 2-10, 13, and 14 are dependent upon claim 1, claims 2-10, 13, and 14 are not anticipated by Saab. Applicants further submit that Saab does not disclose a solid or a gel as recited in instant claim 8.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1-10, and 13-14 under 35 USC § 102(b) as being anticipated by Saab.

The Examiner stated that Saab discloses all elements of claims 22-29 as presented above where the saccular body is the balloon that forms a flexible and inelastic reservoir. The Examiner stated that, further to claim 30, the disclosure by Saab of water or saline as a fluid for circulation and cooling/heating inherently requires a pump.

Anticipation under 35 U.S.C. 102(b) requires the presence in a single prior art disclosure of each and every element of a claimed invention, *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 USPQ2d 1766, 1767 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988).

Applicants respectfully submit that Saab does not disclose a heat exchange catheter system for cooling a target organ comprising a marker. Applicants have amended claim 22 to recite: “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system comprising a transducer, a marker, and an inflatable saccular body, the inflatable saccular body defining a lumen, adapted to conform in shape and size to the interior of an anatomical structure, wherein when placed within the anatomical structure and inflated, the outer surface of the saccular body is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and the lumen of the saccular body, and whereby the target organ adjacent to the anatomical structure is thereby cooled”.

Applicants submit that claim 22 as amended is not anticipated by Saab. Applicants respectfully note that since claims 23, 24, and 25 are dependent upon claim 22, claims 23, 24, and 25 are not anticipated by Saab.

Applicants respectfully submit that Saab does not disclose a device for transesophageal cooling of the heart of a subject comprising a marker. Applicants have amended claim 26 to recite: “A device for transesophageal cooling of the heart of a subject comprising: (a) a reservoir adapted in shape and size to conform to the lumen of the esophagus, (b) a thermal exchange composition disposed within the reservoir, and (c) a transducer, and (d) a marker”. Applicants submit that claim 26 as amended is not anticipated by Saab. Applicants respectfully note that since claims 27, 28, 29, and 30 are dependent upon claim 26, claims 27, 28, 29, and 30 are not anticipated by Saab.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1-10, 13-14, and 22-30 under 35 USC § 102(b) as being anticipated by Saab.

#### Claim Rejections under 35 USC § 103(a)

3) The Examiner has rejected claims 16-21 under 35 USC § 103(a) as being unpatentable over Saab. The Examiner stated that although Saab et al. failed to disclose the specific

cooling rates claimed, the Examiner maintained that even the most rapid (sic) rate of 2-5 degrees per 30 minutes could be realized by the catheter system based upon typical performance of the disclosed coolants, as are well known in the art of heat exchange catheters. In addition, the Examiner maintained that the broad range claims reveals a lack of criticality of the rate and one of ordinary skill in the art would be able to determine such rates by routine experimentation.

Applicants respectfully note that some of the rates encompassed by claim 19 (drawn to a rate of between about 0.5°C/30 minutes and 30°C/30 minutes), such as, for example, a rate of 10°C/30 minutes is more rapid than the rate of between about 2°C/30 minutes and 5°C/30 minutes as disclosed in claim 21.

"Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined."  
*Graham v. John Deere Co.*, 148 USPQ 459, 467 (S.Ct. 1966).

Applicants respectfully submit that the scope and content of the prior art and the claims at issue are different in that Saab does not disclose a heat exchange catheter system comprising a marker. Applicants have amended claim 1 to recite: "A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a transducer 29, (d) a marker 31, and (e) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is

exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”.

Applicants respectfully submit that Saab and the subject matter sought to be patent are different such that the subject matter as a whole would not have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Saab does not disclose a heat exchange catheter system comprising a marker as recited in claim 1 and therefore dependent claims 16-21 are not unpatentable over Saab.

4) The Examiner has rejected claims 1-3, 31 and 33-36 under 35 USC § 103(a) as being unpatentable over Ward et al. (5,531,776). The Examiner stated that Ward et al. disclose all elements of claims 1-3 and the method of use. However, the Examiner continued, Ward et al. failed to specifically disclose a “transducer”, which the applicants had defined as a temperature sensor, and, therefore, the Examiner maintained that at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Ward et al. to include a temperature sensor at the heat exchange region.

The Examiner further stated that although Ward et al. failed to disclose the specific cooling rates claimed, the Examiner maintained that even the most rapid (sic) rate of 2-5 degrees per 30 minutes could be realized by the catheter system based upon typical performance of the disclosed coolants, as are well known in the art of heat exchange catheters. In addition, the Examiner maintained that the broad range claims reveals a lack of criticality of the rate and one of ordinary skill in the art would be able to determine such rates by routine experimentation.

"Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." *Graham v. John Deere Co.*, 148 USPQ 459, 467 (S.Ct. 1966).

Applicants respectfully submit that the scope and content of the prior art and the claims at issue are different in that Ward et al. does not disclose a heat exchange catheter system for cooling a target organ comprising a marker. Applicants have amended claim 1 to recite: “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a transducer 29, (d) a marker 31, and (e) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”.

Applicants have amended claim 31 to recite: “A method of altering the temperature of the myocardium of the heart in a subject, the method comprising the steps of: (a) providing a thermal exchange composition, and (b) placing the thermal exchange composition within the esophagus of the subject, whereby the myocardium of the heart is cooled and wherein the thermal exchange composition is contained within a reservoir and the reservoir comprises a transducer and a marker”.

Applicants respectfully submit that Ward et al. and the subject matter sought to be patent are different such that the subject matter as a whole would not have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Ward et al. do not disclose a heat exchange catheter system comprising a marker as recited in claims 1 and 31 and therefore dependent claim 33 is not unpatentable over Ward et al. Applicants further submit that since claim 34 is a method of using the system of claim 3, claim 3 being dependent upon claim 1, that Ward et al. do



not disclose the method of using a heat exchange catheter system as claimed in claim 34 and therefore dependent claims 35 and 36 are not unpatentable over Ward et al.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1-3, 31 and 33-36 under 35 USC § 103(a) as being unpatentable over Ward et al.

#### Allowable Subject Matter

5) The Examiner objected to claims 11, 12, and 15 as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

Applicants have amended claim 11 to recite: “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, the lumen 8 further comprising a thermal exchange composition, wherein the thermal exchange composition flows within the continuous fluid pathway formed by the second elongate tubular body 2, the first elongate tubular body 1, and the balloon lumen 8 and wherein the thermal exchange composition is selected from the group consisting of a solid, a gel, a liquid, and a gas, (d) a transducer 29, (e) a guide sheath 25 fitted over at least a portion of the first elongate tubular body, and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”. Applicants have rewritten in independent form including all the limitations of the base claim and any intervening claims thereby overcoming the objection of the Examiner of claim 11.

Applicants have amended claim 12 to recite: “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, the lumen 8 further comprising a thermal exchange composition, wherein the thermal exchange composition flows within the continuous fluid pathway formed by the second elongate tubular body 2, the first elongate tubular body 1, and the balloon lumen 8 and wherein the thermal exchange composition is selected from the group consisting of a solid, a gel, a liquid, and a gas, (d) a transducer 29, and wherein the balloon, when inflated, has a longitudinally disposed groove upon its outer surface and is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”. Applicants have rewritten in independent form including all the limitations of the base claim and any intervening claims thereby overcoming the objection of the Examiner of claim 12.

Applicants have amended claim 15 to recite: “A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body 1 having a proximal end and a distal end, (b) a second elongate tubular body 2 having a proximal end and a distal end, (c) a balloon 4 defining a lumen 8 in fluid communication with both the first elongate tubular body 1 and the second elongate tubular body 2 so as to form a continuous fluid pathway, the lumen 8 further comprising a thermal exchange composition, wherein the thermal exchange composition flows within the continuous fluid pathway formed by the second elongate tubular body 2, the first elongate tubular

body 1, and the balloon lumen 8 and wherein the thermal exchange composition is selected from the group consisting of a solid, a gel, a liquid, and a gas, (d) a transducer 29, (e) a third elongate tubular body 3 having a proximal end and a distal end, the third elongate tubular body disposed longitudinally within the second elongate tubular body, and wherein the balloon is sealably affixed to the outer surface of the first elongate tubular body and sealably affixed to the outer surface of the third elongate tubular body, (f) a guidewire disposed longitudinally within the third elongate tubular body, the guidewire having a proximal end and a distal end, (g) a digestible composition 30 affixed at or near the distal end of the guidewire , and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”. Applicants have rewritten in independent form including all the limitations of the base claim and any intervening claims thereby overcoming the objection of the Examiner of claim 15.

Applicants therefore respectfully request that the Examiner withdraw the objection to claims 11, 12 and 15.

## CONCLUSION

With the above amendments and arguments, Applicants submit that the instant application is in condition for allowance.

If the US Patent Office believes that communication would further the prosecution of this application, then the appropriate US Patent Office personnel are invited to contact the Applicants' below-signed representative at their earliest convenience.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Bell & Associates Deposit Account No. 50-3194.

Dated and signed:

31<sup>st</sup> May 2007



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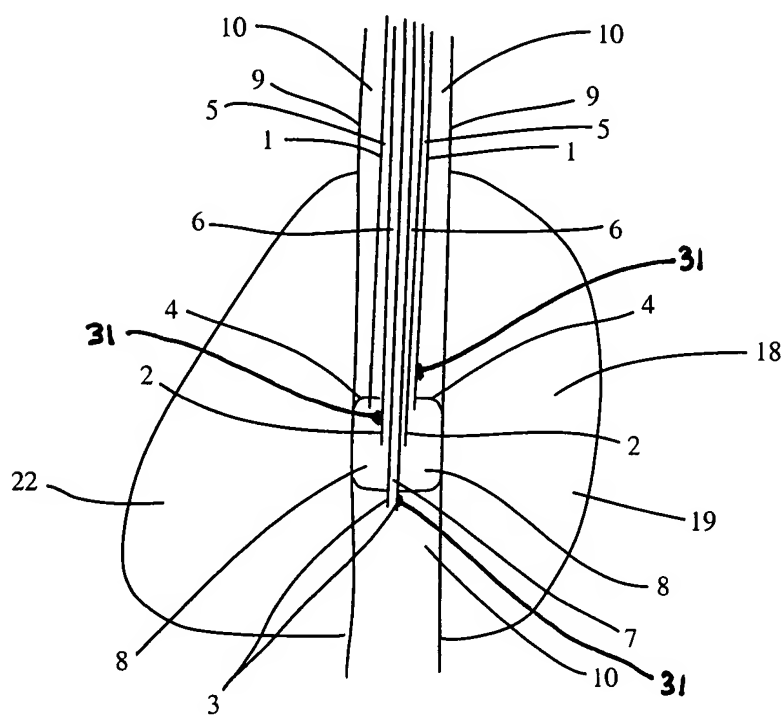


Fig. 8